

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

|  |   |                                      |
|--|---|--------------------------------------|
| <b>NATIONAL ASSOCIATION OF CHAIN</b>             | ) |                                      |
| <b>DRUG STORES and NATIONAL</b>                  | ) |                                      |
| <b>COMMUNITY PHARMACISTS</b>                     | ) |                                      |
| <b>ASSOCIATION,</b>                              | ) |                                      |
|  | ) | Civil Action No. 1:07-cv-02017 (RCL) |
| Plaintiffs,                                      | ) |                                      |
| v.   | ) |                                      |
|  | ) |                                      |
| <b>UNITED STATES DEPARTMENT OF</b>               | ) |                                      |
| <b>HEALTH AND HUMAN SERVICES, <i>et al.</i>,</b> | ) |                                      |
|  | ) |                                      |
| Defendants.                                      | ) |                                      |

**PLAINTIFFS’ REPLY TO DEFENDANTS OPPOSITION TO PLAINTIFFS’  
PROPOSED PRELIMINARY INJUNCTION ORDER**

At a hearing on December 14, 2007, the Court orally imposed a preliminary injunction against Defendants. The Court found that the AMP Rule, and the publication of AMP data calculated pursuant to that rule, would irreparably injure the retail pharmacies that are members of NACDS and NCPA. The Court also found that the Plaintiffs are substantially likely to succeed on the merits of their claims because Defendants have failed to abide by the “crystal clear” provisions of the Social Security Act. In particular, the Court found that the Defendants’ have failed to follow the statutory definitions of “average manufacturer price” and “multiple source drugs.”

The parties have been unable to come to an agreement on a joint proposed order. Earlier today, Defendants submitted their own proposed order. As discussed below, Plaintiffs are willing to compromise on most of the issues raised by Defendants. However, Defendants’ proposed order is flawed because:

1. It would allow Defendants to continue to disclose to the States flawed AMP data calculated under the enjoined AMP Rule, which would harm Plaintiffs’ member pharmacies because States have indicated that they plan to use this AMP data to establish Medicaid reimbursement rates for pharmacies;

2. It ignores the Court’s finding that the Plaintiffs were likely to succeed on the merits of their claim that a federal upper limit on reimbursement for a multiple source drug may not be applied by Defendants in a State unless the drug products used to calculate the federal upper limits are generally available to the public through retail pharmacies “in that State”; and
3. It fails to address all of the elements of the standard for issuing a preliminary injunction, which may result in reversal on appeal for failure to consider all elements of the test for issuing a preliminary injunction.

Plaintiffs have attached a new proposed order that addresses these three important issues.

**I. PLAINTIFFS’ NEW PROPOSED ORDER ADDRESSES DEFENDANTS’ PRINCIPAL CONCERNS WITHOUT ALLOWING DEFENDANTS TO IMPROPERLY HARM PHARMACIES**

The attached proposed order would allow Defendants to continue to implement the AMP Rule for the limited purpose of calculating rebates that drug manufacturers pay to States. Therefore, the attached proposed order eliminates the principal concern raised by Defendants. *See* Defendants’ Opposition To Plaintiffs’ Proposed Preliminary Injunction at 1-4. The attached proposed order also deletes the list of transactions that are improperly included in AMP calculations, which was another concern expressed by Defendants. *See id.* at 4.<sup>1</sup>

**II. AMP DATA SHOULD NOT BE DISCLOSED TO THE STATES**

The principal difference between Defendants’ proposed order and Plaintiffs’ new proposed order concerns disclosure of AMP data to the States. Plaintiffs oppose disclosure of the flawed AMP data to the States or anyone else. The AMP data is fundamentally flawed because Defendants have included many sales transactions in AMP calculations that do not

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<sup>1</sup> Plaintiffs do not share Defendants’ belief “that this Court has not yet made specific findings with respect to any categories of transactions.” *Id.* at 4. Plaintiffs anticipate that the transcript of the hearing will reflect that the Court did make specific findings that certain transactions should not be included in AMP calculations because they do not comply with the statutory definition of “average manufacturer price.”

conform to the statutory definition of AMP. The statute provides that AMP includes only prices paid to manufacturers by wholesalers for covered outpatient drugs distributed to the retail pharmacy class of trade. See 42 U.S.C. § 1396r-8(k)(1). However, As discussed at length during the hearing and in Plaintiffs' briefs, the AMP rule includes many sales transactions that do not fit this statutory definition, such as prices paid by dialysis centers, physicians, mental health clinics, hospitals, patients, and many other individuals and entities.

Disclosure of this AMP data to States and others would harm pharmacies. Nine States have recently indicated that they are "likely" or "very likely" to use these AMP data as the basis for establishing Medicaid reimbursement rates for brand name drugs. See National Association of State Medicaid Directors, *2007 State Perspectives Medicaid Pharmacy Policies and Practice*, 5-6, (attached hereto as Exhibit A).<sup>2</sup> Another 15 states have not ruled out the possibility of using the AMP data to establish reimbursement rates. *Id.* Defendants should not be allowed to distribute AMP data to the States when that flawed data will be used by States to establish reimbursement rates. The entire purpose of the preliminary injunction is to halt attempts to use the flawed AMP data to establish reimbursement rates.

Dr. Schondelmeyer's expert report clearly describes the irreparable harm that would occur if the flawed AMP data are disclosed to payers such as the States. See Schondelmeyer Report at ¶¶ 206-10. That is why the Court has enjoined Defendants from posting AMP data on a website. For similar reasons, Defendants should not be allowed to harm pharmacies by distributing that flawed data to States for use in establishing payment rates for retail pharmacies.

In short, Defendants should not be permitted to make an end run around the injunction barring the AMP web posting by carving out an exception to share the data with the states.

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<sup>2</sup> Available at <http://www.nasmd.org/resources/docs/PharmacyRpt1107.pdf>

Disclosing this flawed data, which was not calculated in accordance with the statute, would harm pharmacies.

**II. DEFENDANTS SHOULD BE REQUIRED TO ABIDE BY THE STATUTORY DEFINITION OF “MULTIPLE SOURCE DRUG”**

The attached proposed order does include the requirement that federal upper limits may not be applied in a State unless the drug products used to establish those federal upper limits are generally available to the public through retail pharmacies in that State. The attached proposed order also includes the requirement that federal upper limits apply only to equivalent multiple source drug products, not to non-equivalent “B-Rated” drug products.

These are statutory requirements with which Defendants must comply. See 42 U.S.C. § 1396r-8(e)(4), (k)(7). Defendants assert that these requirements need not be included in the order because Defendants will not calculate “AMP-based” federal upper limits. However, these statutory requirements are *not* AMP-specific – they apply regardless of whether or not AMP is used as the basis for establishing federal upper limits. These statutory requirements remain in place, as a matter of law, no matter the basis for calculating FULs. It is disturbing that Defendants object to the inclusion of language in a preliminary injunction order that merely requires Defendants to comply with statutory requirements.

**CONCLUSION**

For the reasons identified above, Plaintiffs request that the Court file the proposed order (attached as Exhibit B).

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 15th day of December, 2007, true copies of the foregoing Reply to Defendants Opposition to Plaintiffs' Proposed Preliminary Injunction were served via e-mail and via ECF service on the following:

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/s/ Christopher W. Mahoney  
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